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UNITED STATES DISTRICT COURT FOR THE

NORTHERN DISTRICT OF CALIFORNIA

TIRRELL ALLEN

Plaintiff,

-vs.-

GLOBAL BLOOD THERAPEUTICS, INC. and PFIZER, INC.

Defendants.

CASE NO.:

COMPLAINT FOR DAMAGES FOR

1) STRICT LIABILITY, DESIGN DEFECT;

2) STRICT LIABILITIY, FAILURE TO WARN;

3) NEGLIGENCE;

4) BREACH OF EXPRESS WARRANTIES;

5) BREACH OF IMPLIED WARRANTIES;

6) UNJUST ENRICHMENT;

7) FALSE AND MISLEADING ADVERTISING IN VIOLATION OF BUSINESS & PROFESSIONS CODE §17200, et seq.;

8) FALSE AND MISLEADING ADVERTISING IN VIOLATION OF BUSINESS & PROFESSIONS CODE §17500, et seq.; and

9) VIOLATION OF CALIFORNIA CIVIL CODE §1750, et seq.;

DEMAND FOR JURY TRIAL

Plaintiff Tirrell Allen, by and through the undersigned counsel, brings this civil action against Defendants Global Blood Therapeutics, Inc. and Pfizer, Inc. (hereinafter Defendants) for personal injuries and damages suffered by Plaintiff, and alleges the following:

INTRODUCTION

1. This is an action for damages related to Defendants' wrongful conduct in connection with the development, design, testing, manufacturing, labeling, packaging, promoting, advertising, marketing, distribution, and selling of Oxbryta (generic name: voxelotor), a prescription medication used to treat sickle cell disease (herein after SCD) in adults and children aged 4 and older.

2. Oxbryta is manufactured as an oral, once-daily therapy for patients with SCD.

3. On September 25, 2024, Defendants announced that it was voluntarily withdrawing all lots of Oxbryta, in all markets where it is approved (hereinafter the Recall).[1] The decision came after "data showed an imbalance in Vaso-occlusive crises, a complication of the disease and "fatal events" that required further assessment."[2]

4. Defendants knew or should have known for decades that Oxbryta, when administered and prescribed as intended, can cause or substantially contribute to VOCs and even death.

5. Nevertheless, Defendants failed to warn, instruct, advise, educate, or otherwise inform Oxbryta users and prescribers about the risk of VOCs and/or death.

6. As a proximate result of Defendants' wrongful actions and inactions, Plaintiff was seriously injured after consuming Defendants' Oxbryta products.

7. Plaintiff therefore demands judgment against Defendants and requests, among other things, compensatory damages, statutory damages, punitive damages, attorneys' fees, and costs.

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[1] https://www.pfizer.com/news/press-release/press-release-detail/pfizer-voluntarily-withdraws-all-lots-sickle-cell-disease

[2] https://www.reuters.com/business/healthcare-pharmaceuticals/pfizer-withdraws-sickle-cell-disease-treatment-all-markets-2024-09-25/

PARTIES

8. Plaintiff, Tirrell Allen is a natural person and resident of Illinois. Tirrell Allen brings this suit in his personal capacity.

9. Defendant Global Blood Therapeutics, Inc. is a Delaware corporation, with its principal executive offices located at 181 Oyster Point Boulevard, South San Francisco, California 94080.

10. Defendant, Pfizer, Inc. is a New York corporation that is licensed to do business in all states of the United States of America including the State of California.

11. Defendant Global Blood Therapeutics, Inc. "discovered and developed" Oxbryta, which was granted accelerated approval by the FDA in November 2019.[3]

12. On October 5, 2022, Defendant Pfizer announced the acquisition of Defendant Global Blood Therapeutics, in a transaction "valued at $68.50 per Global Blood Therapeutics share in cash, for a total enterprise value of approximately $5.4 billion."[4]

13. Upon information and belief, Defendant Global Blood Therapeutics is a wholly owned subsidiary of Defendant Pfizer.

14. All Defendants do business in California by, among other things, distributing, marketing, selling and/or profiting from Oxbryta in California as well as throughout the United States.

15. At all times material herein, Defendants were, and still are, pharmaceutical companies involved in the manufacturing, research, development, marketing, distribution, sale, and release for use to the general public of pharmaceuticals, including Oxbryta, in California, and throughout the United States.

JURISDICTION AND VENUE

16. Jurisdiction over this matter is proper in this Court pursuant to 28 U.S.C.A. § 1331 because

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[3] https://www.pfizer.com/news/press-release/press-release-detail/pfizer-completes-acquisition-global-blood-therapeutics

[4] https://www.pfizer.com/news/press-release/press-release-detail/pfizer-acquire-global-blood-therapeutics-54-billion-enhance

of diversity of citizenship of the parties and because the amount in controversy is in excess of $75,000 exclusive of costs and interest.

17. This Court has jurisdiction over Defendant Global Blood Therapeutics, Inc. because their principal place of business is in San Francisco County, California.

18. This Court also has jurisdiction over Defendant Pfizer because they are a business entity that does sufficient business and has minimum contacts in California or otherwise intentionally avail themselves of the California market, through the sale, marketing and use of its products in California, to render the exercise of jurisdiction over it by the California courts consistent with traditional notions of fair play and substantial justice.

19. All Defendants regularly conduct business in California.

20. Plaintiff is a resident and citizen of Illinois.

21. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. § 1367.

22. Venue of this case is proper in California because some or all of the cause of action arose in California.

PLAINTIFF TIRELL ALLEN SPECIFIC FACTS

23. Plaintiff Tirrell Allen is a 43-year old male who was diagnosed with SCD as a child.

24. In approximately August 2024, he began taking Oxbryta for the treatment of SCD.

25. While on Oxbryta, Plaintiff suffered a significant number of side effects, including a higher rate of VOCs than prior to starting the medication, pain, swelling, and other debilitating symptoms all caused by his consumption of Oxbryta.

26. Additionally, in September 2024, while still on Oxbryta, Plaintiff had a VOC and suffered a stroke. Plaintiff is still hospitalized as of the date of this Complaint.

27. As a result of Defendants' actions and inactions, Plaintiff Tirrell Allen was seriously injured while on Oxbryta.

28. At the time of injury, Plaintiff Tirrell Allen was unaware that Oxbryta had a higher rate of vaso-occlusive crisis. He was also unaware that there were more deaths in the Oxbryta treatment group

as compared to the placebo group in post-marketing studies or that there were higher rates of vaso-occlusive crises in patients with sickle cell disease receiving Oxbryta in two real-world registry studies.

GENERAL ALLEGATIONS

Sickle Cell Disease

29. SCD is a group of inherited red blood cell disorders. Red blood cells contain hemoglobin, a protein that carries oxygen. Healthy red blood cells are round, and they move through small blood vessels to carry oxygen to all parts of the body.

30. In someone who has SCD, the hemoglobin is abnormal, which causes the red blood cells to become hard and sticky and look like a C-shaped farm tool called a sickle. The sickle cells die early, which causes a constant shortage of red blood cells. Also, when they travel through small blood vessels, sickle cells get stuck and clog the blood flow. This can cause pain and other serious complications (health problems) such as infection, acute chest syndrome, and stroke.

31. There are several types of SCD. The specific type of SCD a person has depends on the genes they inherited from their parents. People with SCD inherit genes that contain instructions, or code, for abnormal hemoglobin, including:

HbSS: People who have this form of SCD inherit two genes, one from each parent, that code for hemoglobin "S." Hemoglobin S is an abnormal form of hemoglobin that causes the red cells to become rigid, and sickle shaped. This is commonly called sickle cell anemia and is usually the most severe form of the disease.

HbSC: People who have this form of SCD inherit a hemoglobin S gene from one parent and a gene for a different type of abnormal hemoglobin called "C" from the other parent. This is usually a milder form of SCD.

HbS beta thalassemia: People who have this form of SCD inherit a hemoglobin S gene from one parent and a gene for beta thalassemia, another type of hemoglobin abnormality, from the other parent. There are two types of beta thalassemia: "zero" (HbS beta0) and "plus" (HbS beta+). Those with HbS beta0-thalassemia usually have a severe form of SCD. People with HbS beta+-thalassemia tend to have a milder form of SCD.

32. SCD is diagnosed with a simple blood test. In children born in the United States, it most often is found at birth during routine newborn screening tests at the hospital. In addition, SCD can be diagnosed while the baby is in the womb. Diagnostic tests before the baby is born, such as chorionic villus sampling and amniocentesis, can check for chromosomal or genetic abnormalities in the baby. Chorionic villus sampling tests a tiny piece of the placenta called chorionic villus. Amniocentesis tests a small sample of amniotic fluid surrounding the baby.[5]

Oxbryta

33. The active substance in Oxbryta, was supposed to work by improving the ability of the hemoglobin to hold on to oxygen, and preventing it from forming chains. In theory, this would help the red blood cells to maintain normal shape and flexibility, reducing their excess breakdown and improving their lifespan.

34. The FDA approved Oxbryta under the accelerated approval pathway in 2019 for the treatment of sickle cell disease in adults and pediatric patients 12 years of age and older. In 2021, FDA granted accelerated approval of Oxbryta for the treatment of sickle cell disease in patients 4 to 11 years of age. Accelerated approval is based on a surrogate or intermediate clinical endpoint that is reasonably likely to predict clinical benefit, allowing for earlier approval of drugs that treat serious conditions and fill an unmet medical need. In general, FDA requires post-marketing studies to verify and describe the clinical benefit of medications approved under this program. *Id.*

35. Defendants marketed Oxbryta through various forms of media and promised its purchasers would "experience less sickling."[6]

36. Defendant Global Blood Therapeutics called Oxbryta a "firsts-of-its-kind tablet that treats

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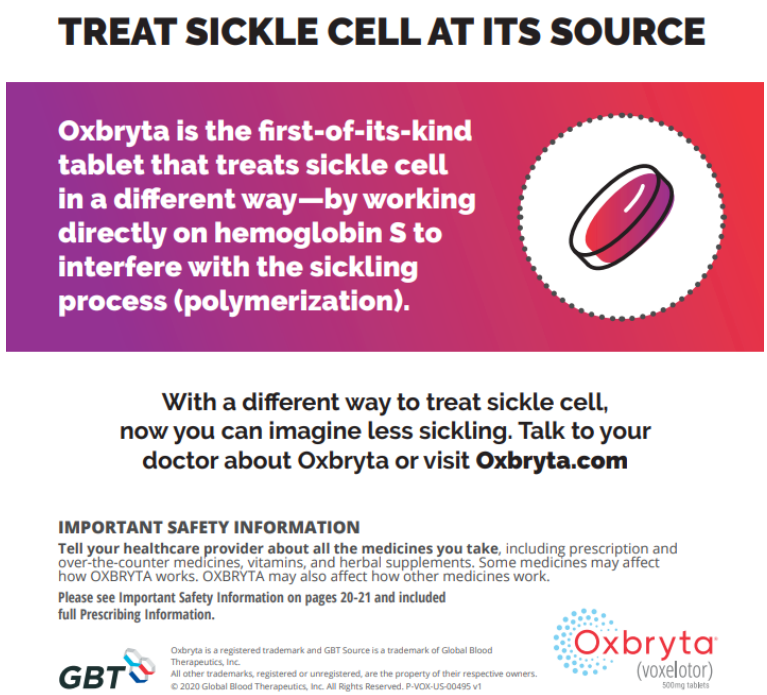
[5] https://www.cdc.gov/sickle-cell/about/index.html#:~:text=Sickle%20cell%20disease%20(SCD)%20is,some%20more%20severe%20than%20others.

[6] https://www.mmm-online.com/home/channel/first-look-oxbryta-spot-aims-to-empower-patients-with-sickle-cell/

sickle cell. . .” and would lead to “less sickling” by “address[ing] sickling at its source.” [7]

[7] https://sicklecellconsortium.org/wp-content/uploads/2020/06/Oxbryta-Core-Patient-Leave-Behind-Electronic-Version-2.pdf



Id.

37. On September 25, 2024, Defendants announced they were voluntarily withdrawing the medication from the market, ceasing distribution, and discontinuing all active clinical trials and expanded access programs for Oxbryta "because recent data indicate the benefit of Oxbryta does not outweigh the risks for the sickle cell patient population."[8]

38. Defendants noted that their decision was "based on the totality of clinical data that now indicates the overall benefit of OXBRYTA no longer outweighs the risk in the approved sickle cell patient population. The data suggest an imbalance in vaso-occlusive crises and fatal events which require further assessment."[9]

39. According to the European Medicines Agency, Study GBT440-032 is assessed the effects

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[8] https://www.fda.gov/drugs/drug-safety-and-availability/fda-alerting-patients-and-health-care-professionals-about-voluntary-withdrawal-oxbryta-market-due

[9] https://www.pfizer.com/news/press-release/press-release-detail/pfizer-voluntarily-withdraws-all-lots-sickle-cell-disease

of voxelotor on the transcranial doppler ultrasound measurements of cerebral arterial blood flow in children from 2 to 15 years of age with SCD and are at high risk of stroke. The study recruited 236 patients from Egypt, Ghana, Kenya, Nigeria, Oman, Saudi Arabia, the United States and the United Kingdom. There were 8 deaths in people taking voxelotor and 2 deaths in people taking placebo.[10]

40. Study GBT440-042 assessed the effects of voxelotor on leg ulcers in 88 patients from 12 years of age recruited from Brazil, Kenya and Nigeria. Eight deaths occurred in the open-label part of this study. *Id.*

41. "The initiation of the review follows an imbalance of deaths between voxelotor and placebo observed in clinical trials," the European Medicines Agency said in an agenda of the meeting posted on its website.[11]

42. Oxbryta was at all times utilized and prescribed in a manner foreseeable to Defendants, as Defendants generated the instructions for use. Plaintiff and his physicians foreseeably used Oxbryta, and did not misuse or alter Oxbryta in an unforeseeable manner.

43. As a direct result of being prescribed and consuming Oxbryta, Plaintiff has been permanently and severely injured, having suffered serious consequences.

44. As a direct and proximate result of his Oxbryta use, Plaintiff suffered severe physical pain and has sustained permanent injuries and emotional distress, along with economic loss including past and future medical expenses.

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[10] https://www.ema.europa.eu/en/documents/referral/oxbryta-article-20-procedure-review-started_en.pdf

[11] https://www.reuters.com/business/healthcare-pharmaceuticals/pfizer-withdraws-sickle-cell-disease-treatment-all-markets-2024-09-25/

CAUSES OF ACTION

COUNT 1

STRICT LIABILITY – DESIGN DEFECT

45. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

46. Plaintiff brings this strict liability claim against Defendants for defective design with respect to their Oxbryta products.

47. At all relevant times, Defendants engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and/or promoting Oxbryta products, which are defective and unreasonably dangerous to consumers, including Plaintiff, thereby placing Oxbryta products into the stream of commerce. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants designed, researched, developed, manufactured, produced, tested, assembled, labeled, advertised, promoted, marketed, sold, and/or distributed the Oxbryta products used by Plaintiff, as described herein.

48. At all relevant times, Defendants' Oxbryta products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by or exposure to the public, including Plaintiff.

49. At all relevant times, Defendants' Oxbryta products reached the intended consumers, handlers, and users or other persons coming into contact with these products within this judicial district and throughout the United States, including Plaintiff, without substantial change in its condition as designed, manufactured, sold, distributed, labeled, and/or marketed by Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, packaged, and/or sold Oxbryta products within this judicial district and aimed at a consumer market within this judicial district. Defendants were at all relevant times involved in the sales and promotion of Oxbryta products marketed and sold in this judicial district.

50. Defendants Oxbryta products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and/or marketed by Defendants were defective in

design and formulation in that, when they left the control of Defendants' manufacturers and/or suppliers, they were unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would contemplate.

51. Defendants' Oxbryta products, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and/or marketed by Defendants were defective in design and formulation in that, when they left the hands of Defendants' manufacturers and/or suppliers, the foreseeable risks exceeded the alleged benefits associated with its design and formulation.

52. At all relevant times, Defendants knew or had reason to know that Oxbryta products were defective and were inherently dangerous and unsafe when used in the manner instructed and provided by Defendant.

53. Therefore, at all relevant times, Defendants' Oxbryta products, as researched, tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold, and/or marketed by Defendants were defective in design and formulation, in one or more of the following ways:

a. When placed in the stream of commerce, Defendants' Oxbryta products were defective in design and formulation, and, consequently, dangerous to an extent beyond that whichan ordinary consumer would contemplate;

b. When placed in the stream of commerce, Defendants' Oxbryta products were unreasonably dangerous in that they were hazardous and posed a grave risk of VOCs and other serious illnesses when used in a reasonably anticipated manner;

c. When placed in the stream of commerce, Defendants' Oxbryta products contained unreasonably dangerous design defects and were not reasonably safe when used in a reasonably anticipated or intended manner;

d. Defendants did not sufficiently test, investigate, or study their Oxbryta products;

e. Exposure to Oxbryta products presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

f. Defendants knew or should have known at the time of marketing/selling Oxbryta products that exposure to Oxbryta could result severe illnesses and injuries and even death;

g. Defendants did not conduct adequate post-marketing surveillance of their Oxbryta products;

h. Defendants could have employed safer alternative designs and formulations.

54. Plaintiff used and was exposed to Defendants' Oxbryta products without knowledge of Oxbryta's dangerous characteristics.

55. At all times relevant to this litigation, Plaintiff used and/or was exposed to the use of Defendants' Oxbryta products in an intended or reasonably foreseeable manner without knowledge of Oxbryta's dangerous characteristics.

56. Plaintiff could not reasonably have discovered the defects and risks associated with Oxbryta products before or at the time of exposure due to the Defendants' suppression or obfuscation of scientific information.

57. The harm caused by Defendants' Oxbryta products far outweighed its benefit, rendering Defendants' product dangerous to an extent beyond that which an ordinary consumer would contemplate. Defendants' Oxbryta products were and are more dangerous than alternative products, and Defendants could have designed Oxbryta products to make them less dangerous. Indeed, at the time Defendants designed Oxbryta products, the state of the industry's scientific knowledge was such that a less risky design or formulation was attainable.

58. At the time Oxbryta products left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Oxbryta products.

59. Defendants' defective design of Oxbryta products was willful, wanton, malicious, and conducted with reckless disregard for the health and safety of users of the Oxbryta products, including Plaintiff.

60. Therefore, as a result of the unreasonably dangerous condition of their Oxbryta products, Defendants are strictly liable to Plaintiff.

61. The defects in Defendants' Oxbryta products were substantial and contributing factors in causing Plaintiff's injuries, and, but for Defendants' misconduct and omissions, Plaintiff would not have

sustained injuries.

62. Defendants' conduct, as described herein, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety problems associated with Oxbryta products, and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, warn or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

63. As a direct and proximate result of Defendants placing their defective Oxbryta products into the stream of commerce, and the resulting injuries, Plaintiff sustained pecuniary loss including general damages in a sum which exceeds the jurisdictional minimum of this Court.

64. As a proximate result of Defendants placing their defective Oxbryta products into the stream of commerce, as alleged herein, there was a measurable and significant interval of time during which Plaintiff has suffered great mental anguish and other personal injury and damages.

65. As a proximate result of the Defendants placing their defective Oxbryta products into the stream of commerce, as alleged herein, Plaintiff sustained loss of income and/or loss of earning capacity.

66. WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor and against Defendants for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT II:

STRICT LIABILITY – FAILURE TO WARN

67. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

68. Plaintiff brings this strict liability claim against Defendants for failure to warn.

69. At all relevant times, Defendants engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and/or promoting Oxbryta products which are defective and unreasonably dangerous to consumers, including Plaintiff, because they do not contain adequate warnings or instructions concerning the dangerous characteristics of Oxbryta. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants

registered, researched, manufactured, distributed, marketed, and sold within this judicial district and aimed at a consumer market. Defendants were at all relevant times involved in the retail and promotion of Oxbryta products marketed and sold in in this judicial district.

70. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce their Oxbryta products, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiff, and therefore had a duty to warn of the risks associated with the use of Oxbryta products.

71. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Oxbryta products did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiff of dangers associated with Oxbryta. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

72. At the time of manufacture, Defendants could have provided warnings or instructions regarding the full and complete risks of Oxbryta products because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products.

73. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote safety or to minimize the dangers to users and consumers of their product and to those who would foreseeably use or be harmed by Defendants' Oxbryta products, including Plaintiff.

74. Even though Defendants knew or should have known that Oxbryta posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure. The dangerous propensities of their products and as a result of ingesting Oxbryta, as described above, were known to Defendants, or scientifically knowable to Defendants through appropriate research and testing by known methods, at the time they distributed, supplied or sold the product, and were not known to end users and consumers, such as Plaintiff.

75. Defendants knew or should have known that their products created significant risks of

serious bodily harm to consumers, as alleged herein, and Defendants failed to adequately warn consumers, i.e., the reasonably foreseeable users, of the risks of exposure to their products. Defendants have wrongfully concealed information concerning the dangerous nature of Oxbryta, and further, have made false and/or misleading statements concerning the safety of Oxbryta products.

76. At all relevant times, Defendants' Oxbryta products reached the intended consumers, handlers, and users or other persons coming into contact with these products within this judicial district and throughout the United States, including Plaintiff, without substantial change in its condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

77. Plaintiff was exposed to Defendants' Oxbryta products without knowledge of its dangerous characteristics.

78. At all relevant times, Plaintiff used and/or was exposed to the use of Defendants' Oxbryta products while using it for its intended or reasonably foreseeable purposes, without knowledge of its dangerous characteristics.

79. Plaintiff could not have reasonably discovered the defects and risks associated with Oxbryta products prior to or at the time of Plaintiff consuming Oxbryta. Plaintiff relied upon the skill, superior knowledge, and judgment of Defendants to know about and disclose serious health risks associated with using Defendants' products.

80. Defendants knew or should have known that the minimal warnings disseminated with their Oxbryta products were inadequate, failed to communicate adequate information on the dangers and safe use/exposure, and failed to communicate warnings and instructions that were appropriate and adequate to render the products safe for its ordinary, intended and reasonably foreseeable uses.

81. The information Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiff to utilize the products safely and with adequate protection. Instead, Defendants disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of and/or exposure to Oxbryta; continued to aggressively promote the efficacy of their products, even after they knew or should have

known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Oxbryta.

82. This alleged failure to warn is not limited to the information contained on Oxbryta's labeling. Defendants should have warned the public about risks associated with Oxbryta through other non-labeling mediums, i.e., promotion, advertisements, public service announcements, and/or public information sources. But Defendants did not disclose these known risks through any medium.

83. Defendants are liable to Plaintiff for injuries caused by their negligent or willful failure, as described above, to provide adequate warnings or other clinically relevant information and data regarding the appropriate use of their products and the risks associated with the use of Oxbryta.

84. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Oxbryta products, Plaintiff could have avoided the risk of developing injuries and could have obtained or used alternative medication.

85. As a direct and proximate result of Defendants placing defective Oxbryta products into the stream of commerce, Plaintiff was injured and has sustained pecuniary loss resulting and general damages in a sum exceeding the jurisdictional minimum of this Court.

86. As a proximate result of Defendants placing defective Oxbryta products

87. into the stream of commerce, as alleged herein, there was a measurable and significant interval of time during which Plaintiff suffered great mental anguish and other personal injuries and damages.

88. As a proximate result of Defendants placing defective Oxbryta products into the stream of commerce, as alleged herein, Plaintiff sustained loss of income and/or loss of earning capacity.

89. WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor and against Defendants for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

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COUNT III:

NEGLIGENCE

90. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

91. Defendants or indirectly, caused Oxbryta products to be sold, distributed, packaged, labeled, marketed, promoted, and/or used by Plaintiff. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed and sold Oxbryta within this judicial district and aimed at a consumer market within this district.

92. At all relevant times, Defendants had a duty to exercise reasonable care in the design, research, manufacture, marketing, advertisement, supply, promotion, packaging, sale, and distribution of Oxbryta products, including the duty to take all reasonable steps necessary to manufacture, promote, and/or sell a product that was not unreasonably dangerous to consumers and users of the product.

93. At all relevant times, Defendants had a duty to exercise reasonable care in the marketing, advertisement, and sale of the Oxbryta products. Defendants' duty of care owed to consumers and the general public included providing accurate, true, and correct information concerning the risks of using Oxbryta and appropriate, complete, and accurate warnings concerning the potential adverse effects of Oxbryta.

94. At all relevant times, Defendants knew or, in the exercise of reasonable care, should have known of the hazards and dangers of Oxbryta.

95. Accordingly, at all relevant times, Defendants knew or, in the exercise of reasonable care, should have known that use of Oxbryta products could cause or be associated with Plaintiff's injuries, and thus, create a dangerous and unreasonable risk of injury to the users of these products, including Plaintiff.

96. Defendants also knew or, in the exercise of reasonable care, should have known that users and consumers of Oxbryta were unaware of the risks and the magnitude of the risks associated with use of Oxbryta.

97. As such, Defendants breached their duty of reasonable care and failed to exercise ordinary

care in the design, research, development, manufacture, testing, marketing, supply, promotion, advertisement, packaging, sale, and distribution of Oxbryta products, in that Defendants manufactured and produced defective Oxbryta; knew or had reason to know of the defects inherent in their products; knew or had reason to know that a user's or consumer's use of the products created a significant risk of harm and unreasonably dangerous side effects; and failed to prevent or adequately warn of these risks and injuries.

98. Defendants were negligent in their promotion of Oxbryta, outside of the labeling context, by failing to disclose material risk information as part of their promotion and marketing of Oxbryta, including the internet, television, print advertisements, etc. Nothing prevented Defendants from being honest in their promotional activities, and, in fact, Defendants had a duty to disclose the truth about the risks associated with Oxbryta in their promotional efforts, outside of the context of labeling.

99. Despite their ability and means to investigate, study, and test the products and to provide adequate warnings, Defendants failed to do so. Indeed, Defendants wrongfully concealed information and further made false and/or misleading statements concerning the safety and use of Oxbryta.

100. Defendants' negligence included:

a. Manufacturing, producing, promoting, formulating, creating, developing,designing, selling, and/or distributing Oxbryta products without thorough and adequate pre- and post-market testing;

b. Manufacturing, producing, promoting, formulating, creating, developing,designing, selling, and/or distributing Oxbryta while negligently and/or intentionally concealing and failing to disclose the results of trials, tests, and studies of Oxbryta;

c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not Oxbryta products were safe for its intended consumer use;

d. Failing to use reasonable and prudent care in the design, research, manufacture, and development of Oxbryta products so as to avoid the risk of serious harm associated with the prevalent use of Oxbryta products;

e. Failing to design and manufacture Oxbryta products so as to ensure they were at least

as safe and effective as other medications on the market intended to treat the same symptoms;

f. Failing to provide adequate instructions, guidelines, and safety precautions to those persons Defendants could reasonably foresee would use Oxbryta products;

g. Failing to disclose to Plaintiff, users/consumers, and the general public that use of Oxbryta presented severe risks of VOCs and other grave illnesses;

h. Failing to warn Plaintiff, consumers, and the general public that the product'srisk of harm was unreasonable and that there were safer and effective alternative medications available to Plaintiff and other consumers;

i. Systematically suppressing or downplaying contrary evidence about the risks, incidence, and prevalence of the side effects of Oxbryta products;

j. Representing that their Oxbryta products were safe for its intended use when, in fact, Defendants knew or should have known the products were not safe for its intended purpose;

k. Declining to make or propose any changes to Oxbryta products' labeling or other promotional materials that would alert consumers and the general publicof the risks of Oxbryta;

l. Advertising, marketing, and recommending the use of the Oxbryta products, while concealing and failing to disclose or warn of the dangers known (by Defendants) to be associated with or caused by the use of or exposure to Oxbryta;

m. Continuing to disseminate information to their consumers, which indicate or imply that Defendants' Oxbryta products are not unsafe for regularconsumer use; and

n. Continuing the manufacture and sale of their products with the knowledge thatthe products were unreasonably unsafe and dangerous.

101. Defendants knew and/or should have known that it was foreseeable consumers such as Plaintiff would suffer injuries as a result of Defendants' failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution, and sale of Oxbryta.

102. Plaintiff did not know the nature and extent of the injuries that could result from the intended use of and/or exposure to Oxbryta.

103. Defendants' negligence was the proximate cause of Plaintiff's injuries.

104. Defendants' conduct, as described above, was reckless. Defendants regularly risked the lives of consumers and users of their products, including Plaintiff, with full knowledge of the dangers of their products. Defendants have made conscious decisions not to redesign, re- label, warn, or inform the unsuspecting public, including Plaintiff. Defendants' reckless conduct therefore warrants an award of punitive damages.

105. As a direct and proximate result of Defendants placing defective Oxbryta products into the stream of commerce, Plaintiff was injured and has sustained pecuniary loss and general damages in a sum exceeding the jurisdictional minimum of this Court.

106. As a proximate result of Defendants placing defective Oxbryta products into the stream of commerce, as alleged herein, there was a measurable and significant interval of time during which Plaintiff suffered great mental anguish and other personal injury and damages.

107. As a proximate result of Defendants placing defective Oxbryta products into the stream of commerce, as alleged herein, Plaintiff sustained a loss of income, and loss of earning capacity.

108. WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor and against Defendants for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT IV:

BREACH OF EXPRESS WARRANTIES

109. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

110. At all relevant times, Defendants engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and/or promoting Oxbryta products, which are defective and unreasonably dangerous to consumers, including Plaintiff, thereby placing Oxbryta products into the stream of commerce. These actions were under the ultimate control and supervision of

Defendants.

111. Defendants had a duty to exercise reasonable care in the research, development, design, testing, packaging, manufacture, inspection, labeling, distributing, marketing, promotion, sale, and release of Oxbryta products, including a duty to:

a. ensure that their products did not cause the user unreasonably dangerous side effects;

b. warn of dangerous and potentially fatal side effects; and

c. disclose adverse material facts, such as the true risks associated with the use of and exposure to Oxbryta, when making representations to consumers and the general public, including Plaintiff.

112. Oxbryta's label confirms that it was "indicated for the treatment of sickle cell disease in adults and pediatric patients 4 years of age and older."[12]

113. As alleged throughout this pleading, the ability of Defendants to properly disclose those risks associated with Oxbryta is not limited to representations made on the labeling.

114. Defendants marketed Oxbryta through various forms of media and promised its purchasers would "experience less sickling."[13]

115. At all relevant times, Defendants expressly represented and warranted to the purchasers of their products, by and through statements made by Defendants in labels, publications, package inserts, and other written materials intended for consumers and the general public, that Oxbryta products were safe to human health and the environment, effective, fit, and proper for its intended use. Defendants advertised, labeled, marketed, and promoted Oxbryta products, representing the quality to consumers and the public in such a way as to induce its purchase or use, thereby making an express warranty that Oxbryta products would conform to the representations.

116. These express representations include incomplete warnings and instructions that purport,

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[12] https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/213137s006lbl.pdf

[13] https://www.mmm-online.com/home/channel/first-look-oxbryta-spot-aims-to-empower-patients-with-sickle-cell/

but fail, to include the complete array of risks associated with use of and/or exposure to Oxbryta. Defendants knew and/or should have known that the risks expressly included in Oxbryta warnings and labels did not and do not accurately or adequately set forth the risks of developing the serious injuries complained of herein. Nevertheless, Defendants expressly represented that Oxbryta products were safe and effective, that they were safe and effective for use by individuals such as the Plaintiff, and/or that they were safe and effective as consumer medication.

117. The representations about Oxbryta, as set forth herein, contained or constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, creating an express warranty that the goods would conform to the representations.

118. Defendants placed Oxbryta products into the stream of commerce for sale and recommended its use to consumers and the public without adequately warning of the true risks of developing the injuries associated with the use of Oxbryta.

119. Defendants breached these warranties because, among other things, Oxbryta products were defective, dangerous, and unfit for use, did not contain labels representing the true and adequate nature of the risks associated with its use, and were not merchantable or safe for its intended, ordinary, and foreseeable use and purpose. Specifically, Defendants breached the warranties in the following ways:

a. Defendants represented through their labeling, advertising, and marketing materials that Oxbryta products were safe, and intentionally withheldand concealed information about the risks of serious injury associated with useof Oxbryta and by expressly limiting the risks associated with use within its warnings and labels; and

b. Defendants represented that Oxbryta products were safe for use and intentionally concealed information that demonstrated that Oxbryta could lead to higher risks of VOCs and death.

120. Plaintiff detrimentally relied on the express warranties and representations of Defendants concerning the safety and/or risk profile of Oxbryta in deciding to purchase the product. Plaintiff reasonably relied upon Defendants to disclose known defects, risks, dangers, and side effects of Oxbryta.

Plaintiff would not have purchased or used Oxbryta had Defendants properly disclosed the risks associated with the product, either through advertising, labeling, or any other form of disclosure.

121. Defendants had sole access to material facts concerning the nature of the risks associated with their Oxbryta products, as expressly stated within its warnings and labels, and knew that consumers and users such as Plaintiff could not have reasonably discovered that the risks expressly included in Oxbryta warnings and labels were inadequate and inaccurate.

122. Plaintiff had no knowledge of the falsity or incompleteness of Defendants' statements and representations concerning Oxbryta.

123. Plaintiff used and/or was exposed to Oxbryta as researched, developed, designed, tested, manufactured, inspected, labeled, distributed, packaged, marketed, promoted, sold, or otherwise released into the stream of commerce by Defendants.

124. Had the warnings, labels, advertisements, or promotional material for Oxbryta products accurately and adequately set forth the true risks associated with the use of such products, including Plaintiff's injuries, rather than expressly excluding such information and warranting that the products were safe for its intended use, Plaintiff could have avoided the injuries complained of herein.

125. As a direct and proximate result of Defendants' breach of express warranty, Plaintiff has sustained pecuniary loss and general damages in a sum exceeding the jurisdictional minimum of this Court.

126. As a proximate result of Defendants' breach of express warranty, as alleged herein, there was a measurable and significant interval of time during which Plaintiff suffered great mental anguish and other personal injury and damages.

127. As a proximate result of Defendants' breach of express warranty, as alleged herein, Plaintiff sustained a loss of income and/or loss of earning capacity.

128. WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor and against Defendants for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

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COUNT V:

BREACH OF IMPLIED WARRANTIES

129. Plaintiff incorporates by reference every allegation set forth in preceding paragraphs as if fully stated herein.

130. At all relevant times, Defendants engaged in the business of testing, developing, designing, manufacturing, marketing, selling, distributing, and/or promoting Oxbryta products, which were and are defective and unreasonably dangerous to consumers, including Plaintiff, thereby placing Oxbryta products into the stream of commerce.

131. Before the time Plaintiff used Oxbryta products, Defendants impliedly warranted to their consumers, including Plaintiff, that Oxbryta products were of merchantable quality and safe and fit for the use for which they were intended; specifically, as consumer medication.

132. But Defendants failed to disclose that Oxbryta has dangerous propensities when used as intended and that use of Oxbryta products carries an increased risk of developing severe injuries, including Plaintiff's injuries.

133. Plaintiff was an intended beneficiary of the implied warranties made by Defendants to purchasers of their Oxbryta products.

134. The Oxbryta products were expected to reach and did in fact reach consumers and users, including Plaintiff, without substantial change in the condition in which they were manufactured and sold by Defendants.

135. At all relevant times, Defendants were aware that consumers and users of their products, including Plaintiff, would use Oxbryta products as marketed by Defendants, which is to say that Plaintiff was a foreseeable user of Oxbryta.

136. Defendants intended that Oxbryta products be used in the manner in which Plaintiff, in fact, used them and which Defendants impliedly warranted to be of merchantable quality, safe, and fit for this use, even though Oxbryta was not adequately tested or researched.

137. In reliance upon Defendants' implied warranty, Plaintiff used Oxbryta as instructed and labeled and in the foreseeable manner intended, recommended, promoted, and marketed by Defendants.

138. Plaintiff could not have reasonably discovered or known of the risks of serious injury associated with Oxbryta.

139. Defendants breached their implied warranty to Plaintiff in that Oxbryta products were not of merchantable quality, safe, or fit for its intended use, or adequately tested. Oxbryta has dangerous propensities when used as intended and can cause serious injuries, including those injuries complained of herein.

140. The harm caused by Defendants' Oxbryta products far outweighed its benefit, rendering the products more dangerous than an ordinary consumer or user would expect and more dangerous than alternative products.

141. As a direct and proximate result of Defendants' breach of implied warranty, Plaintiff has sustained pecuniary loss and general damages in a sum exceeding the jurisdictional minimum of this Court.

142. As a proximate result of the Defendants' breach of implied warranty, as alleged herein, there was a measurable and significant interval of time during which Plaintiff suffered great mental anguish and other personal injury and damages.

143. As a proximate result of Defendants' breach of implied warranty, as alleged herein, Plaintiff sustained a loss of income and/or loss of earning capacity.

144. WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor and against Defendants for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT VI:

UNJUST ENRICHMENT

145. Plaintiff incorporates by reference every allegation set forth in preceding paragraphs as if fully stated herein.

146. At all relevant times, Defendants designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold, or otherwise released Oxbryta products into the stream of commerce, and therefore owed a duty of reasonable care to avoid causing harm to those that

consumed it, including Plaintiffs.

147. Defendants were unjustly enriched as a result of their wrongful conduct, including through the false and misleading marketing, promotions, and advertisements that omitted disclosure that the products presented an unreasonable risk of substantial bodily injury resulting from its use.

148. Defendants appreciated, recognized, and chose to accept the monetary benefits Plaintiff conferred onto Defendants at Plaintiff's detriment. These benefits were the expected result of Defendants acting in their pecuniary interests at the expense of Plaintiffs.

149. There is no justification for Defendants' enrichment. It would be inequitable, unconscionable, and unjust for Defendants to be permitted to retain these benefits because the benefits were procured as a result of their wrongful conduct.

150. Defendants wrongfully obfuscated the harm caused by their Oxbryta products. Thus, Plaintiffs, who mistakenly enriched Defendants by relying on Defendants' misrepresentations of product safety, could not and did not know the effect that using Oxbryta products would have on Plaintiffs' health.

151. Plaintiff is entitled to restitution of the benefits Defendants unjustly retained and/or any amounts necessary to return Plaintiff to the position they occupied prior to dealing with Defendant. Plaintiff would expect compensation from Defendants' unjust enrichment stemming from their wrongful actions.

152. WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor and against Defendants for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT VII

FALSE AND MISLEADING ADVERTISING IN VIOLATION OF BUSINESS & PROFESSIONS CODE §17200, *et seq.*

153. Plaintiff incorporates by reference every allegation set forth in preceding paragraphs as if fully stated herein.

154. This cause of action is brought pursuant to Business and Professions Code §17200, *et seq.*

155. In the advertising of the Oxbryta Products, Defendants made false and misleading

statements and material omissions including, as set forth above, the representation that its Oxbryta products would lead to "less sickling" by "address[ing] sickling at its source."

156. Defendants are aware that the claims that it makes about their Oxbryta products are false, misleading, and unsubstantiated.

157. As alleged in the preceding paragraphs, Defendants' misrepresentations and omissions of the material facts detailed above constitute an unfair and fraudulent business practice within the meaning of California Business & Professions Code §17200.

158. In addition, Defendants' use of various forms of advertising media to advertise, call attention to or give publicity to the sale of goods or merchandise, which are not as represented in any manner, constitute unfair, deceptive, untrue or misleading advertising, unfair competition, and an unlawful business practice within the meaning of Business & Professions Code §§17531 and 17200, which advertisements have deceived and are likely to deceive the consuming public, in violation of Business & Professions Code §17500.

159. There were reasonably available alternatives to further Defendants' legitimate business interests, other than the conduct described herein.

160. All of the conduct alleged herein occurs and continues to occur in Defendants' business. Defendants' wrongful conduct is part of a pattern or generalized course of conduct repeated on thousands of occasions daily.

161. Pursuant to Business & Professions Code §§17203 and 17535, Plaintiff seeks an order requiring Defendants to disclose such misrepresentations, and additionally seeks an order awarding Plaintiff restitution of the money Defendants wrongfully acquired by means of responsibility attached to Defendants' failure to disclose the existence and significance of said misrepresentations.

162. Thus, Plaintiff has suffered and will continue to suffer injuries and damages for which they are entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs, and attorneys' fees.

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COUNT VIII

FALSE AND MISLEADING ADVERTISING IN VIOLATION OF BUSINESS & PROFESSIONS CODE §17500, *et seq.*

163. Plaintiff incorporates by reference every allegation set forth in preceding paragraphs as if fully stated herein.

164. This cause of action is brought pursuant to Business and Professions Code §17500, et seq. (the "FAL"). The FAL prohibits the dissemination of any advertisement which is untrue or misleading, and which is known, or which by exercise of reasonable care should be known, to be untrue or misleading. Cal. Bus. & Prof. Code §17500.

165. In its advertising of Oxbryta products, Defendants made false and misleading statements. Specifically, as set forth above, Defendants labeled its products as safe and effective for the treatment of SCD.

166. In fact, the Oxbryta products injurious to consumers. Defendants are aware that its claims regarding the Oxbryta products are false, misleading, and unsubstantiated.

167. As alleged in the preceding paragraphs, the Defendants' misrepresentations of the material facts detailed above constitute an unfair and fraudulent business practice within the meaning of the FAL.

168. In addition, Defendants' use of various forms of advertising media to advertise, call attention to, or give publicity to the sale of goods or merchandise, which are not as represented in any manner, constitutes unfair, deceptive, untrue or misleading advertising, unfair competition, and an unlawful business practice within the meaning of Business & Professions Code §§ 17531 and 17200, which advertisements have deceived and are likely to deceive the consuming public, in violation of the FAL.

169. Pursuant to Business & Professions Code §§17203 and 17535, Plaintiff seeks an order requiring Defendants to disclose such misrepresentations, and additionally request an order awarding Plaintiff restitution of the money that Defendants wrongfully acquired by means of responsibility attached to Defendants' failure to disclose the existence and significance of said misrepresentations.

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COUNT IX

VIOLATION OF CALIFORNIA CIVIL CODE §1750, *et seq.*

170. Plaintiff incorporates by reference every allegation set forth in preceding paragraphs as if fully stated herein.

171. This cause of action is brought pursuant to Civil Code §1750, et seq., the Consumers Legal Remedies Act.

172. Plaintiff constitutes a "consumer" within the meaning of Civil Code §1761(d).

173. Defendants' sales of the Oxbryta products constitute "transactions" within the meaning of Civil Code §1761(e).

174. The Oxbryta products purchased by Plaintiff constitutes "goods" under Civil Code §1761(a).

175. The policies, acts, and practices heretofore described were intended to result in the sale of Oxbryta products to the consuming public and violated and continue to violate: (1) Section 1770(a)(5) of the Act which prohibits, inter alia, "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have;" (2) Section 1770(a)(7) of the Act, which prohibits, "[r]epresenting that goods or services are of a particular standard, quality, grade, or that goods are of a particular style or model , if they are of another;" (3) Section 1770(a)(9), which prohibits, '[a]advertising goods or services with intent not to sell them as advertised" and section 1770(a)(14) which prohibits "representing that a transaction confers or involves rights, remedies, or obligations which it does not have or involve."

176. Defendants fraudulently deceived Plaintiff by representing that Oxbryta products have certain characteristics, benefits, uses and qualities which it does not have. In doing so, Defendants intentionally misrepresented and concealed material facts from Plaintiff, specifically and not limited to the fact that its Oxbryta products promote health and are fit for consumption. Said misrepresentations and concealment were done with the intention of deceiving Plaintiff and depriving him of his legal rights and money.

177. Defendants knew that the Oxbryta products were contaminated and not safe for

consumption.

178. Defendants' actions as described hereinabove were done with conscious disregard of Plaintiff's rights and Defendants were wanton and malicious in their concealment of the same.

179. Pursuant to California Civil Code §1780(a) of the Act, Plaintiff seeks injunctive relief in the form of an order enjoining the above-described wrongful acts and practices of Defendants including, but not limited to, an order enjoining Defendants from distributing such false advertising and misrepresentations. Plaintiff shall be irreparably harmed if such an order is not granted.

180. Plaintiff reserves the right to amend this complaint to include a request for damages under the CLRA after complying with California Civil Code §1782(a) within thirty days after the commencement of this action.

IV. PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for a jury trial and for judgment against Defendants, and each of them, as follows **FOR ALL CAUSES OF ACTION:**

1. For past, present and future general damages in an amount to be determined at trial;
2. For past, present and future special damages, including but not limited to past, present and future lost earnings, economic damages and others, in an amount to be determined at trial;
3. Any appropriate punitive or exemplary damages;
4. Any appropriate statutory damages;
5. For costs of suit;
6. For interest as allowed by law;
7. For attorney's fees and costs as applicable;
8. For treble damages as applicable;
9. For such other and further relief as the court may deem proper.

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Respectfully submitted,

Dated: November 7, 2024

BRADLEY/GROMBACHER LLP
AYLSTOCK, WITKIN, KREIS & OVERHOLTZ

By: /s/ *Kiley Grombacher*
Marcus J. Bradley, Esq.
Kiley L. Grombacher, Esq.
S. Mary Lie, Esq.
Attorneys for Plaintiff

DEMAND FOR JURY TRIAL

Plaintiff Tirrell Allen demands a jury trial in this matter.

Dated: November 7, 2024

BRADLEY/GROMBACHER LLP
AYLSTOCK, WITKIN, KREIS & OVERHOLTZ

By: /s/ *Kiley Grombacher*
Marcus J. Bradley, Esq.
Kiley L. Grombacher, Esq.
S. Mary Lie, Esq.
Attorneys for Plaintiff